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08/702,525

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/702,525	02/07/97	SHARPE	BWI-120CPUS

EXAMINER: A

HM22/1207

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ART UNIT: 1644 | PAPER NUMBER: 21

DATE MAILED: 12/07/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6/11/99 ; 9/10/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 18-29, 32, 48-59, 62, 66-68, 73-74, 78-82 is/are pending in the application.
Of the above, claim(s) 18-29, 32, 48-59, 64, 66-68, 73-74 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 78-82 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Detailed Action

1. The request filed 9/10/99 (Paper No. 20) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/702,525 is acceptable and a CPA has been established An Action on the CPA follows.

2. Applicant's amendment, filed 9/10/99 (Paper No. 20), is acknowledged.
Claims 1-17, 30-31, 33-47, 60-61, 63-65, 69-71 and 75-77 have been canceled.
Claims 78-82 have been added.

Claims 18-29, 32, 48-59, 62, 66-68, 72-74 have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 78-82 are under consideration.

3. Applicant's arguments and amendments, filed 6/11/99 (Paper No. 17) and filed 9/10/99 (Paper No. 20), have been fully considered. Applicant's arguments have been fully considered but are not found convincing as it applies to the current claims under consideration and the rejection set forth herein.

4. The Abstract from the PCT is acknowledged; however this application does not contain an Abstract of the disclosure as required by 37 CFR 1.72(b). An Abstract on a separate sheet is required.

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 78-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the B7-1 or B7-2 T cell costimulatory encoding nucleic acids shown in SEQ ID NO: 18 or SEQ ID NO: 22, does not reasonably provide enablement for any alternative splice forms of a transcript of a B7-1 or B7-2 T cells costimulatory gene, the nucleotide sequence being a naturally occurring variant of the nucleotide sequence shown in SEQ ID NO: 18 or SEQ ID NO: 22 and being represented by a formula A-B-C-D-E", including the "negative limitations/provisos", encompassed by claims 78-82.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims. Applicant has not provided sufficient biochemical information (e.g. nucleic acid sequences, etc.) that distinctly identifies the alternative spliced B7-1/B7-2 variants or naturally occurring variants other than those encompassed by set forth in SEQ ID NOS; 18/22. While "B7-1" and "B7-2" may have some notion of the activity of the polypeptide encoded by the claimed nucleic acids ; "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of Genentech, Inc. v. Novo Nordisk, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Support for certain alternative splice forms of B7-1 are disclosed in the specification as filed. Beyond such limited disclosure; the specification appears to merely assert the existence of other alternatively spliced variants or naturally occurring allelic variants. The claims are not limited to clearly defined number of nucleic acids encoding alternatively spliced or naturally occurring variants of B7-1/B7-2 nucleic acids, but extend to an ill-defined number of species which share one or more functional or structural characteristics with the known B7-1 or B7-2 molecules. Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed protein in manner reasonably correlated with the scope of the claims broadly including any number of alternative spliced forms or naturally occurring variants of B7-1 and B7-2. The scope of the claims must bear a reasonable correlation with the scope of enablement. The specification does not provide for sufficient enablement for alternative spliced forms or naturally occurring variants of B7-1 and B7-2 other than those defined by SEQ ID NOS. 18/22. Without such information, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

10. Claims 78-82 are rejected under 35 U.S.C. § 102(e) as being anticipated by Freeman et al. (U.S. Patent No. 5,942,607). Freeman et al. teach mouse and human B7-1/B7-2 encoding nucleic acids, including that it will be expected that DNA sequence polymorphisms that do lead to change in the amino acid sequence of B7 antigens will exist within a population and that one skilled in the art that the variations will be up to about 3-4% for the nucleotides due to natural allelic variations; and including nucleic acids capable of hybridizing with nucleic acids herein as well as those that are used in screening protocols to detect novel proteins which are cross-reactive with those B lymphocyte activate antigen (see entire document, including column 7, paragraphs 1-2). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced nucleic acids and modified or alternative forms thereof. Given the allelic variations known and expected in the prior art, the prior art nucleic acids would have provided for nucleic acids that would meet the hybridization conditions and would not be exactly those SEQ ID NOS. set forth in the provisos. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced nucleic acids

11. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Patent Examiner
Technology Center 1600
December 2, 1999
Phillip Gambel